## REMARKS

Claim 1 has been amended to recite a "powder composition in the form of solid droplets having an average diameter of about 80 to about 120 nanometers (nm)." Support for this amendment is found in the specification at, for example, page 4, lines 20-23 and in original claims 1 and 2. *See*, *In re Gardner*, 177 USPQ 396, 397 (CCPA 1973) and MPEP §§ 608.01(o) and (l).

It is submitted that no new matter has been introduced by the foregoing amendment. Approval and entry of the amendment are respectfully solicited.

## Rejections Under 35 USC § 103

Claims 1 and 3-15 were rejected under 35 USC §103(a) as being unpatentable over Stein *et al.*, EP 0 937 412 ("Stein") **or** Stein in view of Ford *et al.*, U.S. Patent No. 5,507,707 ("Ford"). (Paper No. 13 at 3.)

Stein discloses "a continuous process for the preparation of a pulverous carotenoid, retinoid or natural colourant preparation, wherein the active ingredient is finely divided ...." (Abstract). The process includes "the steps of

> a) forming a suspension of the active ingredient in a water-inmiscible organic solvent optionally containing an antioxidant and/or an oil,
> b) feeding the suspension of step a) to a heat exchanger and heating said suspension to 100-250°C, whereby the residence time in the heat exchanger is less than 5 sec,
> c) rapidly mixing the solution of step b) at a temperature in the range of 20-100°C with an aqueous solution of a swellable colloid optionally containing a stabilizer,
> d) removing the organic solvent and
> e) converting the dispersion of step d) into a pulverous preparation. (Col. 2, lines 3-16.)

The "finely divided" starting material is said to be of "a particle size of less than 1.5 micron, preferably less than 1 micron, more preferably less than 0.4 micron." (*Id.*, lines 18-21.) Stein further discloses that the "swellable colloid" can include gelatin, carbohydrates, dextrin, pectin, gun arabic, octenylbutanedioate amylodextrin, milk proteins, and vegetable protein, or mixtures thereof. (Col. 3, lines 2-8.) Stein also discloses that powders formed from the compositions are soluble in cold water and provide coloration. (*See*, Examples 1-5.)

Ford discloses "[a]n aqueous composition for the preparation of optically clear products for use in human or animal healthcare comprising 0.1 to 2.0% w/w of an oil-soluble ingredient as a 20-30% w/w dispersion in a suitable oil or 0.1 to 5.0% w/v as the pure crystalline compound, 2-20% of an emulsifier having an HLB (hydrophilic/lipophilic balance) value of between 10 and 18 or where a blend of emulsifiers is employed, a calculated HLB value of between 10 and 18 and 0.1 to 1.0% of an antioxidant or a mixture of antioxidants." (Abstract.) Ford discloses that its compositions are "particularly useful" for producing optically clear products; but that the compositions may be used to produce opaque, cloudy materials as well. (Col. 3, lines 57-59.) Ford further discloses that a variety of other optional ingredients may be added to the compositions or the final food product, including "sweeteners, preservatives (*eg.* sulphur dioxide, benzoic acid and sorbic acid), proteins, fats, vitamins, minerals and other materials employed in the preparation of food and drink products." (Col. 4, lines 34-38.)

In making the rejection, the Examiner asserted that Stein discloses "powder compositions having carotenoids and antioxidants such as vitamin E dispersed

in a matrix of gum arabic or gelatin at particle sizes of about 225 nm. The powders of [Stein] are soluble into beverages and provide for administration of vitamins in this manner (i.e. beverages)." (Paper No. 13 at 4).

The Examiner relied on Ford as disclosing "optically clear beverages obtained when powder compositions having particles less than 650 nm are added." (*Id.*)

The Examiner then concluded that "a *prima facie* case of obviousness exists even though the claimed range and prior art do not overlap, because they are close enough that one skilled in the art would expect them to have the same properties (see MPEP 2144.05 *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ 773)." (*Id.*)

For the reasons set forth below the rejection, respectfully is traversed.

Initially, we note that the Examiner's reliance on *Titanium Metals* is misplaced. The Board in *Ex parte Friedman*, 1996 WL 1748649, *2 (BPAI 1996) (unpublished) reversed an examiner for making a similar rejection. There, the Board explained:

> According to the examiner, it would have been obvious to use a lower annealing temperature as claimed in either of Ikushima or Sawyer since '... the claimed ranges and prior art do not overlap but are close enough that one skilled in the art would have expected them to have the same properties...' (answer, page 4). ***In our view, however, the case law cited by the examiner in support of this proposition, Titanium Metals Corp. v. Banner, 778 F.2d 775, 782, 227 USPQ 773, 779 (Fed. Cir. 1985) does not establish a universal rule regarding the obviousness of 'close enough ranges'.... As stated by the Federal Circuit in In re Ochiai, 71 F.3d 1565, 1572, 37 USPQ2d***

***1127, 1133 (Fed. Cir. 1995) 'reliance on per se rules of obviousness is legally incorrect and must cease.'***

*Id. See also Ex parte Bryant*, 2002 WL 31003032, *1-2 (BPAI 2002) (unpublished) (reversing an examiner for misplaced reliance on *Titanium Metals*).

An obviousness analysis requires an Examiner to identify the motivation or suggestion to modify a cited document to arrive at the claimed invention as a whole. Because the rejections rely on a *per se*, "close enough" standard to circumvent this requirement the rejection is deficient as a matter of law. The rejection identifies no disclosure in Stein or Ford that describes or suggests that the claimed droplet diameters and the particle sizes identified in the cited documents would have the same properties. As is well settled, obviousness is a fact based analysis. The rejection, however, is devoid of any facts – technical analysis or citation to the documents relied upon by the Examiner – to support its conclusion.

Moreover, as in Friedman, where the Board cautioned against ignoring facts in favor of a *per se* rule, the rejection fails to recognize that the difference between the claimed range of 80 -120 nm and the 225 nm identified by the Examiner (Paper No. 13 at 4) is substantially larger than the difference in *Friedman* between the claimed range (0.3% Mo and 0.8% Ni) and the prior art range (0.25 Mo and 0.75% Ni), (0.05%).

Furthermore, we note that Stein discloses a range of particle sizes for the "finely divided" starting material of less than 1.5 micron (1,500 nm), preferably less than 1 micron (1,000 nm) and more preferably 0.4 micron (400 nm) (Col. 2, lines 18-21) and Ford discloses a calculated particle size of not greater than about 0.65 μm (650 nm). The documents relied upon by the Examiner disclose end points that are approximately

4-, 6-, 10-, and 15-fold higher than the claimed range. Thus, the ranges disclosed by Stein and Ford encompass a very large range of possible distinct compositions, which do not disclose or suggest the specific range claimed. *See e.g., In re Jones*, 21 USPQ2d 1941, 1943 (Fed. Cir. 1992).

For all these reasons, the rejections of Stein and Stein in view of Ford are deficient as a matter of fact and law and should be withdrawn.

Notwithstanding the legally insufficient nature of the rejections, we demonstrate below why the rejections are also devoid of the requisite facts to support a *prima facie* case under § 103.

As is fundamental, a *prima facie* case of obviousness must be based on facts, "cold hard facts." *In re Freed*, 165 USPQ 570, 571-72 (CCPA 1970). When the rejection is not supported by facts, it cannot stand. *Ex parte Saceman*, 27 USPQ2d 1472, 1474 (BPAI 1993). In the absence of a *prima facie* case of obviousness, an applicant who complies with the other statutory requirements is entitled to a patent. *See In re Oetiker,* 24 USPQ2d 1443, 1444 (Fed. Cir. 1992).

Further, "to establish *prima facie* obviousness of a claimed invention, all claim limitations must be taught or suggested by the prior art." MPEP § 2143.03 (8th ed. Rev. 1, February 2003, p. 2100-128) (citing *In re Royka*, 180 USPQ 580 (CCPA 1974)).

As amended claim 1 recites a "powder composition in the form of solid droplets having an average diameter of about 80 to about 120 nanometers (nm)."

With respect to the Stein/Ford rejection, we also note that if a proposal for modifying one or more documents renders such documents inoperable or destroys their

intended purpose, then the requisite motivation to make the modification would be nonexistent, and any rejection based on such a proposed modification would have to fail. *See, e.g., In re Fritch*, 23 USPQ2d 1780, 1783, n. 12 (Fed. Cir. 1992) and *In re Ratti*, 123 USPQ 349, 352 (CCPA 1959) (holding the suggested combination of references improper under § 103 because it "would require a substantial reconstruction and redesign of the elements shown in [a prior art reference] ***as well as a change in the basic principles under which [that reference's] construction was designed to operate***.")

Here, Ford discloses an aqueous composition but does not disclose a powder composition ***dispersed in a matrix***, which is disclosed by Stein. In other words, the "powder compositions" disclosed in Ford **are not** made up of powder compositions ***dispersed in a matrix***. In addition, the rejection identifies no disclosure in Stein of "optically" clear solutions, let alone "optically" clear beverages. To modify Ford, in the way the Examiner suggests, would require ignoring the express teachings of the reference. But as noted above, it is impermissible to modify a document to fundamentally alter the principles under which it was designed to operate.

Moreover, even if Ford could be combined with Stein as the Examiner urges, the mere fact that the teachings found in the prior art *could be combined* does not make the combination obvious absent some teaching, suggestion, or incentive supporting the proposed combination. Recently, the Board in *Ex parte Metcalf*, 67 USPQ2d 1633, 1635 (BPAI 2003) explained:

> The U.S. Court of Appeals for the Federal Circuit has stated that '[t]he mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the

> modification obvious unless the prior art suggested the desirability of the modification.' *In re Fritch*, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992) (citing *In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984)). ***Although this statement is couched in terms of modifying the prior art, we hold that a similar one applies to combining teachings found in the prior art. Specifically, the mere fact that teachings found in the prior art could be combined as proposed by an examiner does not make the combination obvious 'absent some teaching, suggestion or incentive supporting the combination.'*** *Carella*, 804 F.2d at 140, 231 USPQ at 647 (citing *ACS Hosp. Syss., Inc.*, 732 F.2d at 1577, 221 USPQ at 933). In the instant appeal, the examiner fails to identify any such teaching, suggestion, or incentive to support his proposed combination. Therefore, we reverse the rejection of claims 1, 2, 4-10, 12-15, 17-19, and 21-55 as obvious over the combination of Murry and Paroutaud.

Here, too, the record is devoid of any such "teaching, suggestion or incentive supporting the combination" of Stein in view of Ford. The Examiner combined Stein with Ford based upon the Examiner's own conclusion that the references *could* be combined, rather than on any teaching or suggestion from either reference. Combining references in this manner is directly counter to the Board's holding *Metcalf*.

For this additional reason, the rejection should be withdrawn.

Claims 1 and 7-15 were rejected under 35 USC §103(a) as being unpatentable over Tritsch *et al.*, EP 0 841 010 ("Tritsch '010") **or** Tritsch '010 in view of Ford. (Paper No. 13 at 4.)

Initially, we note that the Examiner relies on Tritsch '010, which is a German language EP patent publication. Instead of obtaining an English translation of Tritsch '010, the Examiner relied on U.S. Patent No. 6,071,963 ("Tritsch '963") as a translation of Tritsch '010. (Paper No. 13 at 4-6.)

We respectfully submit that the Examiner's reliance on Tritsch '963 as an accurate translation of Tritsch '010 is misplaced because he has failed to show any relationship between the EP document cited and the U.S. patent offered as a translation.

The only apparent relationship between the EP document and the U.S. patent is that they both claim priority to the same Swiss priority application. The later-in-time U.S. application does not claim benefit to the EP document cited by the Examiner. Where, as here, there is no direct relationship between a foreign patent document that may qualify as prior art and a U.S. patent, the Examiner bears the initial burden to demonstrate the propriety of using the proffered U.S. patent as a faithful translation of the asserted document. *See*, MPEP § 901.05(III) (8th ed. Rev. 1, February 2003, p. 900-8 to 900-9) (Noting that related patents often do not contain the same disclosure: "In some instances the second application could have its disclosure diminished or increased, to meet the requirements or practices in the second country; and that in the case where a potential English translation supposedly exists "[q]uestions as to content ... must be settled based on the specification which was used as a reference."); *see also* MPEP § 706.02 (8th ed. Rev. 1, February 2003, p. 700-20 to 700-21) (Stressing the importance of obtaining translations of foreign language documents "because all patentability determinations are fact dependent, obtaining and considering full text documents at the earliest practicable time in the examination process will yield the fullest available set of facts upon which to determine patentability, thereby improving quality and reducing pendency.") The Examiner has made no findings of fact to determine what, if anything, was added to or subtracted from the EP publication

when it was filed in the U.S. Thus, the rejection is based on the hope or belief that Tritsch '010 and Tritsch '963 disclose the same subject matter. Accordingly, the rejection fails to meet the evidentiary burden required to present a *prima facie* case under § 103.

For this reason alone, it is respectfully submitted that all of the rejections based on Tritsch '010 be withdrawn.

With a view toward furthering prosecution, and without waiving the above position, we address the rejections in the Office Action as based on Tritsch '963 patent.

Tritsch '963 discloses "stable, cold water dispersible preparations of fat-soluble substances contain a microbially produced oil rich in arachidonic acid. These preparations are manufactured by preparing an aqueous emulsion of the microbially produced oil which has been stabilized with an antioxidant and fish gelatin and if desired converting this emulsion into a dry powder. The preparations in accordance with the invention can be used for human nutrition." (Abstract.) The pulverous preparation is made a matrix of fish gelatin and then emulsifying a single cell oil (SCO) rich in arachidonic acid stabilized with antioxidant in the gelatin. (Col. 1, lines 61-65.) The emulsion may be converted into a powder using conventional process, *e.g.*, spray drying. (Col. 2, lines 27-30.) These preparations are disclosed to be suitable for human nutrition, especially neonates. (*Id.*, lines 38-39.) The average particle size of the internal phase of the emulsion is disclosed to be 180 nm or 200 nm. (*See*, Example 1, col. 2, line 53 and Example 2, col. 3, lines 1-2.) The antioxidant stabilizer for the oil phase may be tocopherol, an ascorbic acid ester, or a mixture thereof. (Col. 1, lines 37-40.)

Ford is summarized above.

In making the rejection, the Examiner relies on Tritsch as disclosing "powder compositions having vitamins dispersed in a matrix of gelatin at particle sizes of about 200 nm. The powders of [Tritsch] are soluble into beverages and provide for administration of vitamins in this manner (i.e. beverages)." (Paper No. 13 at 4.)

The Examiner, again, relied on Ford as disclosing "optically clear beverages obtained when powder compositions having particles less than 650 nm are added." (*Id.*)

The Examiner once again concluded that "a *prima facie* case of obviousness exists even though the claimed range and prior art do not overlap, because they are close enough that one skilled in the art would expect them to have the same properties (see MPEP 2144.05 *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ 773)." (*Id.*)

The Examiner's reasoning for this rejection is the same as his reasoning for the rejections over Stein. (*Supra.*) Therefore, all arguments made above apply with equal force to this rejection.

The Examiner's reliance on *Titanium Metals* is misplaced. *See, again, Ex parte Friedman*, 1996 WL 1748649, *2 (BPAI 1996) (discussed above).

Moreover, the rejection identifies nothing in the in Tritsch '963 or Ford, which discloses or suggests droplets within a range of 80 to 120 nm as recited in amended claim 1.

The Examiner has not identified where in Tritsch '963 there is disclosed a powder composition with the presently claimed emulsion forming compositions in

combination with a fat soluble vitamin in the form of droplets having a diameter of 80-120 nm as recited in claim 1. Nor has the rejection identified why such a powder composition would have been suggested by Tritsch '963 to one skilled in the art.

Moreover, Ford discloses the use of an aqueous composition but does not disclose a powder composition ***dispersed in a matrix***, which Tritsch '963 discloses. In addition, the rejection identifies no disclosure in Tritsch '963 of "optically" clear solutions, let alone "optically" clear beverages. Therefore, even if Ford could be combined with Tritsch '963 as the Examiner urges, the mere fact that the teachings found in the prior art *could be combined* does not make the combination obvious absent some teaching, suggestion, or incentive supporting proposed combination. *See, again, Ex parte Metcalf*, 67 USPQ2d 1633, 1635 (BPAI 2003) (discussed above).

In sum, for the reasons set forth above the rejections based on Tritsch alone or in combination with Ford should be withdrawn.

Claim 17 was rejected under 35 USC § 103(a) as being unpatentable over Stein or Tritsch '010 each alone or in combination with Ford in view of Finnan *et al.*, U.S. Patent No. 4,830,859 ("Finnan"). (Paper No. 13 at 5.)

Stein is summarized above.

Tritsch is summarized above.

Ford is summarized above.

Finnan discloses "a process for preparing lubricated ***water-soluble vitamin*** powder ... [which] is directly compressible into tablets." (Col. 1, lines 10-15.)

In making the rejection, the Examiner relied on his previous characterization of Stein '412, Tritsch '010, and Ford '707. (Paper No. 13 at 5.)

The Examiner acknowledged, however, that "[n]one of these teaches incorporating the powder into tablets." (*Id.*)

To fill the acknowledged gap, the Examiner relied on Finnan '859 as disclosing "formation of vitamin powder into tablets." (*Id.*)

The Examiner then summarily concluded "it would have been obvious ... to form the powder into tablets with the motivation of providing a convenient dosage form for administration of a vitamin." (*Id.*)

The Examiner's reasoning for this rejection is the same as his reasoning for the rejections over Stein '412 and Tritsch '010 (alone or in combination with Ford '707). Therefore, all arguments made above apply with equal force to this rejection.

With respect to the rejections based on Stein or Tritsch alone, we note that the rejection(s) provide no factual or legal analysis to explain why these documents render claim 17 obvious in view of the admission that neither Stein not Tritsch disclose tableting the disclosed compositions. The rejection provides no evidence from Stein or Tritsch or any technical reasoning to even suggest that the disclosed compositions could be tableted. Nor does the rejection explain whether the Stein or Tritsch composition could be tableted alone or whether additional components would have to be added. Nor does the rejection explain whether further specialized tableting procedures would have to be employed. In short, the rejection(s) provide no factual support to support the ultimate conclusion of unpatentability. As explained above, however, when a rejection is no based on facts, it cannot stand. *In re Freed*, 165 USPQ 570, 571-72 (CCPA 1970) (A *prima facie* case of obviousness must be based on facts, "cold hard facts."); *Ex parte Saceman*, 27 USPQ2d 1472, 1474 (BPAI 1993)

(When the rejection is not supported by facts, it cannot stand.) For this reason, the rejection based on Stein or Tritsch alone should be withdrawn. We also note that a rejection under § 103 must demonstrate ***where*** in the cited documents there was a suggestion which would have "strongly motivated" one to carry out the invention as claimed. *Ex parte Graselli*, 231 USPQ 393, 394 (Bd. App. 1986). The type of motivation which would have "***impelled***" one to do so (*Ex parte Levengood*, 28 USPQ2d 1300, 1301-02 (BPAI 1993)), and the type of suggestion that the changes "***should***" be made. *Ex parte Markowitz*, 143 USPQ 303, 305 (Bd. App. 1964).

Finnan discloses processes for preparing lubricated ***water-soluble vitamins***. The Stein, Tritsch, and Ford documents relied upon by the Examiner disclose active agents that are oil soluble. And, the rejection fails to identify any disclosure in any of the cited documents to suggest that oil-soluble and water-soluble active agents are interchangeable. Nor does the rejection identify any disclosure or suggestion in the cited documents that the compositions of Stein, Tritsch, and Ford – containing oil-soluble actives – are amenable to direct compression onto tablets in the manner that the water-soluble actives of Finnan are. Absent such disclosure or suggestion in any of the documents, the rejection is supported solely by examiner conjecture. An Examiner's belief or conjecture, however, is no substitute for statutory prior art. *In re Kratz*, 201 USPQ 71, 76 (CCPA 1979) (citing *In re Antonie*, 195 USPQ 6 (CCPA 1977) ("We have previously rejected the argument that undirected skill of one in the pertinent art is an adequate substitute for statutory prior art.").) For this reason alone, the rejection is deficient and should be withdrawn.

Notwithstanding the lack of motivation or suggestion to combine the documents in the manner suggested, even in combination, the cited documents fall short of the claimed invention. As noted earlier, the rejection identifies nothing in the disclosure of Stein or Tritsch '963 either alone or in combination with Ford which discloses or suggests a "powder composition in the form of solid droplets having an average diameter of about 80 to about 120 nanometers (nm)." And, the rejection has identified no disclosure in Finnan that would remedy this factual gap.

Accordingly, the suggested modification of Stein or Tritsch '010 either alone or in combination with Ford and combination with Finnan is improper. For this additional reason, the rejection is factually deficient and should be withdrawn.

**Obviousness-type Double Patenting Rejection:**

Claims 1, 3-6, 10-15, and 17 were "rejected under the judicially created doctrine of obviousness-type double patenting ... over claims 1-32 of U.S. Patent No. 6,162,474." (Paper No. 13 at 6.) While not agreeing with the Examiner's position with respect to the double patenting rejection, to advance prosecution, should the § 103 rejections be withdrawn and the only rejection remaining be the obviousness-type double patenting rejection, a terminal disclaimer will be filed to overcome the rejection.

Accordingly, for the reasons set forth above, entry of the amendment, withdrawal of the rejections, and allowance of the claims are respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on November 14, 2003.

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